REMARKS

Claims 1-23 are pending in this application. Claims 15-21 have been withdrawn from consideration. Claims 1-14, 22 and 13 have been rejected. Claims 1 and 22 have been amended in this paper.

Claims 1-4, and 9 were rejected under 35 U.S.C. § 102(b) as anticipated by or in the alternative, under 35 U.S.C. §103(a) as obvious over Beard (U.S. Published Patent Application No. 2002/0005047). Claims 7, 8, and 10-14 were rejected under 35 U.S.C. § 103(a) as obvious over Beard. Claims 5, 22, and 23 were rejected under 35 U.S.C. § 103(a) as obvious over Beard and in view of Ishibe (U.S. Patent No. 5,230,348). Claim 6 was rejected under 35 U.S.C. § 103(a) as obvious over Beard alone or in view of either Iwai et al. (U.S. Patent No. 5,334,294) or Wang et al. (U.S. Patent No. 6,375,826). These rejections are respectfully traversed. Applicant respectfully disagrees with any grounds for rejection not specifically addressed below.

Applicant relies here on the responses filed previously, namely, that since the references do not teach or suggest all of the claim limitations (e.g., ingot A(f) range, percent cold work, level of impurities, the final cold work step of less than 30%, etc.), the examiner has not established prima facie obviousness.

The examiner asserted in a previous Office action that the burden has shifted to applicant to show that steps associated with the claims result in a product materially different from that disclosed in Beard. In response thereto, applicant has submitted for the examiner's consideration a Rule 1.132 declaration and a supplemental Rule 1.132 declaration of a person skilled in the art who has taken over the project that the co-inventors were working on that led to the patent application. The declarant is Craig Mar, Principal Engineer at assignee Paracor Medical, Inc.

In paragraph 7, at page 5 of the current Office action, the examiner poses a question: "a) Precisely what is the difference between materials according to the

invention and those of the prior art, i.e. do they have a longer cyclical tensile fatigue life or do they have a longer rotary beam fatigue life?" Applicant's response is that the claimed invention is directed to a wire, ribbon, sheet or tubing made of a nickel-titanium alloy having long fatigue life. That long fatigue life can be measured and manifests itself through a variety of tests, such as the rotary beam test or the cyclical tensile test, both described in applicant's specification. Accordingly, the longer fatigue life of the present invention product will appear as a longer rotary beam fatigue life and a longer cyclical tensile fatigue life.

To clarify the claims in response to the examiner's point raised in paragraph b) on page 6 of the Office action, applicant has amended claims 1 and 22 to define a long fatigue life. As for the October 20, 2003 entry in Anuja Patel's notebook showing an average of 19077 cycles to failure (as per the examiner note that 19077 "being significantly less than 20,000 cycles), it is applicant's understanding that many tests on many lots were conducted so there are lots that resulted in slightly less than 20,000 mean cycles to failure, but those deviations were not statistically significant, hence the claim recites "*mean* cycles to failure," not just "cycles to failure."

Finally, there is another way to look at the Beard nitinol versus the long fatigue life nitinol of the present invention. As applicant has noted before, the Beard reference is directed to jewelry making which uses nitinol wires that can be fashioned into decorative pieces. The nitinol specified in paragraphs 0006-0007 of Beard are essentially "off the shelf" grade nitinol.

In contrast, applicant Paracor Medical, Inc., is engaged in the design and manufacture of medical devices, which in this instance is a nitinol sleeve that is deployed to cover and constrain the heart of a patient sick with congenital heart failure. The nitinol sleeve compresses the heart as it beats, which cycles the nitinol over and over (described in applicant's specification). For such a medical purpose, applicant is not and cannot risk using "off the shelf" jewelry grade nitinol disclosed in the Beard reference. The jewelry

grade Beard nitinol does not in fact have the long fatigue life suitable for applicant's medical purpose, where a fatigue failure in the sleeve while implanted in a patient could lead to serious health complications or death. Thus, the claimed process results in the high fatigue life medical grade product that is materially different from the jewelry grade nitinol disclosed in Beard.

In response to the rejection of claim 6, although electropolishing may have been known by jewelers in the past, the specific techniques to electropolish in order to remove surface imperfections and near surface inclusions may be different than electropolishing to achieve a shiny cosmetic effect. Put another way, one could electropolish a wire to achieve a nice cosmetic result or a smooth surface of a desired shape, but the wire would still have a poor fatigue life because the electropolishing did not result in a surface finish sufficient to be fatigue resistant; the cosmetic surface shine may still have microscopic surface inclusions from which a fatigue fracture can grow.

For the reasons given above and in applicant's preceding responses, the claim rejections should be withdrawn.

In view of the foregoing, applicant respectfully submits that all claims are now in condition for allowance. Reexamination and reconsideration of the application are respectfully requested and allowance at an early date is solicited. The Commissioner is

authorized to charge Deposit account No. 06-2425 for any unforeseen additional fees arising from the filing of this paper.

Respectfully submitted,

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